

Strict Liability for the Product of COVID-19 Vaccine as a form of Human Rights Protection from the State to the Consumer

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ABSTRACT

The government as the representative of the State must provide the highest standard of protection in the health sector as an effort to fulfill human rights as written in Article 28 H and Article 28 I of the 1945 Constitution of the Republic of Indonesia. In 2021, the Indonesian Government rolled out a mass Covid-19 Vaccination Program in an attempt to stop the spread of the virus and prevent the worst social and economic situation. This policy is considered to be quite good and responsive. But on the other hand, the Government needs to reconsider the rights of vaccine consumers based on the Law of the Republic of Indonesia Number 8 of 1999 on Consumer Protection (UUPK). Nowadays, the responsibility of business actors for a product still requires an element of error that causes detriment to consumers which is certainly unfair to consumers because the Covid-19 vaccine might be made without any element of error. So, in the current form of dependents, it is difficult for the public as consumers to demand accountability for the effects of the vaccine. Vaccine providers will refuse to be responsible for vaccine side effects on the pretext that there was no mistake in the manufacture of the vaccine. For this reason, it deemed necessary to implement strict liability on Covid-19 vaccine products as an effort to fulfill human rights in the public health sector. This study aims to examine the ratio legis and logical framework for the implementation of strict liability to protect human rights and protect consumers from the side effects of the Covid-19 vaccine. This research uses the normative legal research method. The result of this research requires the application of Strict Liability to protect consumers of Covid-19 vaccine products.

Keywords: Covid-19 Vaccine, Strict Liability, Human Rights, Law of the Republic of Indonesia Numb.8 of 1999 on Consumer Protection.

1. INTRODUCTION

The *Coronavirus* disease (COVID-19) Pandemic has found out various new legal phenomena in Indonesia. Within this article, the authors are going to discuss state responsibilities for the mass COVID-19 vaccination programs and the probability of strict liability doctrine implementation as a form of human rights protection given by the government. Referring to Article 12 of the International Economic, Social and Cultural Covenant (ICESCR) stated that “States recognize the right of everyone to the enjoyment of the highest standards of physical and mental health”. [1] The authors believe, public as the consumers of the COVID-19 vaccine have guarantees of these rights.

The term of vaccination in Indonesia has been found in Law Number 4 of 1984 on Infectious Disease

Outbreaks. This regulation has not been revoked and applied in the midst of the current outbreak of the COVID-19 pandemic. Although in practice several additional regulations have been issued by the Government due to the rapid development of the COVID-19 response. One of them is through the Minister of Health Regulation of the Republic of Indonesia (Permenkes) Number 10 of 2021 concerning the Implementation of Vaccination in the Context of Combating the 2019 Corona Virus Disease (Covid-19) Pandemic. This policy is the latest and most updated regulation which regulates the implementation of vaccination in Indonesia.

Vaccination aims at prevention and immunity. It is an effort to prevent and immunize people and their environment so that they do not contract the disease. In its implementation, various dimensions of legal issues

that may arise from the implementation of the vaccination itself can be found, one of which is known as Adverse Event Following Immunization (AEFI). Vaccination products as medical products probably have side effects on users (consumers). AEFI is an important concern, considering some research shows that adverse events following immunization can result in death (even though really small number).

In order to ensure the protection of consumers, Indonesia already has Law Number 8 of 1999 concerning Consumer Protection (Indonesia Consumer Protection Law) which regulates consumer and producer rights and responsibilities in Indonesia. However, in the scheme of the national vaccination accountability relation pattern that occurred in the midst of an outbreak, it was quite different. As regulated in Article 46 of the Minister of the Health Regulation of The Republic of Indonesia Number 10 Year 2021 Concerning Implementation of Vaccination in the Framework of Pandemic Management Corona Virus Disease 2019 (Covid-19) it states that *“Government takes over all the legal responsibilities of the vaccine provider.”* Meanwhile, in the derivative regulation *Minister of Health of The Republic of Indonesia Regulation Number 12 of 2017 Concerning Immunization* has developed a special group as a body system to analyze the effects or side effects of post-vaccine. The task force will process reports and complaints from the public experiencing the effects of AEFI.

However, consumers still have the right to consider another alternative settlement of their reports by filling out a lawsuit through the courts. If the consumers use their right to file a lawsuit, the court must be able to ensure the highest protection for the consumers. The concept of strict liability is the alternative to be implemented by the court. The authors would like to explain the main legal reasons why strict liability can be implemented by the court and how this principle also ensures the full fulfillment of consumers' rights through this article.”

2. RESEARCH METHOD

The author used a type of normative research with the statute approach and conceptual approach research methods. Normative research will analyze the relationship between legal norms to produce a systematic explanation. [2] As for the statute approach research method, the writer analyzes the correlation between the research theme and the related laws and regulations. This aims to test the consistency and suitability of statutory regulations and an *a quo* policy. Meanwhile, the conceptual approach is based on the doctrine and views of experts developing in legal science as a reference in building legal arguments to answer existing legal issues.

The research materials used in this research are Law of the Republic of Indonesia Number 8 of 1999 on Consumer Protection), The United Nations International Covenant on Economic, Social and Cultural Rights 1966, The Civil Code of Indonesia, The 1945 Constitution of

the Republic of Indonesia, Law of the Republic of Indonesia Number 4 of 1984 on Infectious Disease Outbreaks, Judge's Decision in the case of *Rylands v. Fletcher* (1866) and other related regulations. Books and journals are also used to strengthen and complete the arguments in this study. “Torts: Doctrine of Strict Liability Meets A Comparative Negligence Statute” by J. Corbett, “Tort Law and Mass Immunization Programs: Lessons from the Polio and Flu Episodes” by J. Marc, “Applying Strict Liability To Professionals: Economic And Legal Analysis” by F.J. Vandall, and other books and articles relevant to this research.

3. FINDING AND DISCUSSION

3.1. Implementation of Strict Liability on Consumer Protection

3.1.1. Strict Liability

In both tort and criminal law, strict liability exists when a defendant is liable for committing an action, regardless of what his/her intent or mental state was when committing the action. [3] This is the basis of the legal doctrine that holds an individual or organization responsible for damage caused whether they have intent or not. [4] The term strict liability was first found in the Judge's Decision in the case of *Rylands v. Fletcher* (1866). In that case, Plaintiff felt aggrieved because the construction of an artificial lake by defendant had flooded the plaintiff's mining land. [5] The Defendant defended himself, claiming that his actions did not meet the element of negligence because he used professional workers to build the reservoir. However, Judge Blackburn J considered that even though the defendant's actions did not meet the elements of error or negligence, the defendant must still be responsible for the losses caused by him, because the defendant's action in the form of building a reservoir is a high-risk or dangerous activity that has the potential of losses. [6] Therefore, the element of error is no longer needed in demanding accountability. The judge declares Liability without requiring this element of error as Strict Liability.

This doctrine and principle are mostly used in environmental law cases in Indonesia. Professor of Environmental Law at Maastricht University, The Netherlands, Prof. Michael Faure [7] explained that the concept of Strict Liability is actually very simple, the plaintiff does not need to prove whether the company violated the law causing environmental damage or not. This concept was also adopted in Law Number 4 of 1982 which was renewed in Law Number 32 of 2009 concerning Protection and Management of the Environment and also in Law Number 10 of 1997 concerning Nuclear Energy. Furthermore, Article 88 of Law No. 32 of 2009 concerning Environmental Protection and Management, said that the principle of

absolute responsibility (Strict Liability) is "Everyone whose actions, business and / or activities use /produced/managed Toxic and Hazardous Waste (B3) that pose a serious threat the environment are is absolutely responsible for the losses incurred without the need to prove the element of error ". Furthermore, in the explanation of Article 88, it is explained that "What is meant by "strict liability is an element of error that does not need to be proven by the plaintiff as a basis for paying compensation."

The implementation of the strict liability principle in Indonesian laws and regulations has actually been initiated to be amplified by community groups and academics. This encouragement stems from consumer consideration over product liability regulations that have been implemented in 2007, the Indonesian Consumer Protection Agency sent an open letter to Indonesia's Minister of Trade, requesting that the strict liability principle be incorporated into the Indonesian Consumer Protection Law, as well as a position paper[8] Therefore, in the context of making amendments to this regulation, the issue of strict liability has become the concept which is deemed necessary to be implemented immediately. Considering that this recommendation has actually been submitted since 2007 and the Academic Manuscript has been prepared since 2013. However, in its development, this draft has stalled and is no longer a priority agenda of the DPR-RI. So that through this paper, the authors hope to raise the issue on the adoption of strict liability, especially of health sector issues.

3.1.2 An Adverse Event Following Immunization (AEFI)

Vaccine side effects, also referred to as Adverse Events. Following Immunization (AEFI) is any of the following that may arise after vaccination. [9] There is no such thing as a "perfect" vaccine which protects everyone who receives it and is entirely safe for everyone. Effective vaccines (i.e. vaccines inducing protective immunity) may produce some undesirable side effects which are mostly mild and clear up quickly. [10] When AEFI occurs in patients/ communities, patients can experience some illness from minor illness, disability, and even death, which can also occur or be at risk like other medical procedures. AEFI is very rare, but it is still possible to happen anywhere and to anyone. AEFI can also occur in mass immunization programs or government programs as well as immunizations that are requested individually.

Based on the level of symptoms, the side effects of vaccines can be classified into three different sides: [11]

- a) Mild side effects Examples are pain at the injection site, swelling at the injection site, flu, mild fever, heartburn, weakness, dizziness, decreased appetite and others.
- b) Moderate side effects Examples are a severe fever above 38.8 degrees Celsius, seizures, brain swelling, low platelet count, etc.
- c) Severe side effects. The possibility of a person experiencing severe side effects is extremely rare.

The Center for Disease Control and Prevention (CDC) or the United States Department of Health states that the likelihood of this happening is 1 in 1 million people who receive immunizations. The effects of immunization at a very high and serious level are: Severe allergic reactions that can lead to death and Intussusception from the rotavirus vaccine (intestinal obstruction).

Vaccine can impact some people who have allergic reaction. They might get a serious reaction (as mentioned in point a-c) after getting a vaccine jab. Caused by various issues, due to procedural errors, practices in the administration of the vaccine or also due to other causes that are unknown or do not come from the vaccine. Because no vaccine is completely 100% safe. For this reason, legal protection and consumer protection are needed for the community as vaccine users.

3.1.3 Indonesian Mass Vaccination Program

In term of the Pandemic COVID-19 situation, Indonesia has been holding a mass vaccination program since the first month of 2020. [12] Based on the Indonesian Health Regulation, said that the State through the State-Owned Company will take over the production as well as legal responsibility for the impact of the vaccine. Technically, the mandate is then regulated in the Minister of Health of the Republic of Indonesia Regulation Number 12 of 2017 Concerning Immunization. In this case, it means that the Government acts as a business actor who must be responsible for the products it provides. Although vaccinations received by the public are currently subsidized by the State, this condition does not necessarily eliminate the Government's responsibility to vaccine consumers who in this case experience AEFI. The state subsidy system for vaccines given to the public is considered a fulfillment of state obligations as regulated in Article 28 H paragraph (1) of the 1945 Constitution (constitution)

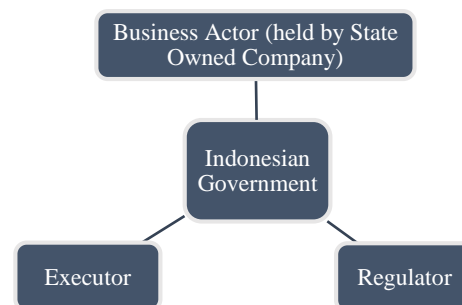


Figure 1 Indonesian State Actor on Vaccination

However, the authors argue that this theory should be used in responding to AEFI, especially in the midst of a health emergency declared by the State. The State represents 3 (three) elements at once, as the Producers, Policy makers and at the same time has a moral responsibility for the protection of people's lives.

However, the vaccine consumer protection guarantee cannot be compared with the urgency of COVID-19 vaccination itself. Government should have the same priority to make sure the national mass vaccination program either protection of vaccination consumers. Thus, the current practice has not shown the government's focus on providing full guarantees for the community to demand the right to health protection as guaranteed by the constitution and other national and international legal provisions.

3.2 State Responsibility to vaccine consumer

3.2.1 Indonesian National Vaccine Regulation

For several hundred years, strict liability has applied in blasting cases, where the neighboring landowner was helpless to avoid the damage. Strict liability has also been applied in many products liability cases where the consumer is helpless to avoid the effects of the defective product. [13]

In Indonesia, the policy system for purchasing, distributing and implementing vaccines nationally is fully controlled by the state. The government has issued several policies related to the implementation of vaccines as previously reviewed. Specifically talking about AEFI, Indonesia has regulations stipulated in the Decree of the Minister of Health Number H.K.01.07 / Menkes / 9860/2020 concerning the Determination of Vaccines for the Implementation of Corona Virus Disease 2019 (Covid-19) Vaccination. The author also uses the policy of the Law of The Republic Of Indonesia Number 8 Of 1999 Consumer Protection has not applied the principle of strict liability, thus making it difficult for consumers to demand compensation (lawsuit to court), must be able to prove the element of error of business actors. Based on the Presidential Decree, it has also specifically regulated an AEFI prevention system in the National scheme as stated in the Minister of Health of the Republic of Indonesia Regulation Number 12 of 2017 Concerning Immunization and is described briefly in the following figure:

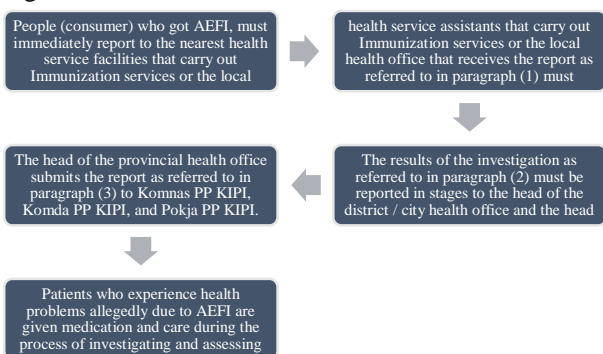


Figure 2 The Minister of Health of the Republic of Indonesia Regulation Number 12 of 2017 concerning Immunization governs the AEFI Mechanism Process

3.2.3 State Responsibilities to Vaccine consumer

We appreciate the Government that has formed the National Forum for the Prevention of AEFI, as an effort to accelerate the handling of AEFI. But for sure, this scheme should not deter consumers who still have objections to the decision and want to continue their case in a lawsuit concerning consumer protection. Given that, this right is also guaranteed by Indonesia's Consumer Protection Law.

The appeal of the Court of Justice of Paraná (TJPR) portray the first-degree decision that the judge dismissed the action as unfounded because he found that the plaintiff did not have a proven causal link between the harm and the vaccine. According to the judge's understanding, there is no evidence that the author had reports proving his fertility prior to the event cited, in order to make it possible to establish that there is a causal link between his vaccination and his subsequent infertility. Similar conditions also appear to be occurring in Indonesia. From 30 cases reported by consumers, not one has ever won (plaintiff). Everything was won by the state, a statement conveyed by the Chairman of the KIP National Committee, Hindra Irawan Satari in the General Hearing Meeting (RDPU) with the Indonesian People's Representative Council. However, when a question arose from one of the members related to how Consumers would be able to prosecute the AEFI effects of vaccines, he did not answer it and recommended asking the competent expert. [14]

The public as consumers are required to vaccinate to help the Government deal with the pandemic. But consumers also have rights and obligations. The right to comfort security and safety is the main focus. The government needs to pay attention to consumer rights related to the Covid 19 vaccination program, which includes: providing vaccine safety information, disseminating an opinion-complaint information system and legal responsibility for the side effects of the Covid-19 vaccine. Henny also explained that if there were problems or losses due to the use of vaccines, the application of compensation as an absolute responsibility of the state (Strict Liability) was very necessary and important for the Indonesian people as consumers, he said in closing the discussion.

In the midst of the health emergency established by the State in 2019, the State together with all other stakeholders in health services have a crucial role to provide national health protection guarantees to the public. Provision of vaccine services is also intended as part of preventive public health measures and services. However, as previously explained, no medical intervention is 100% risk-free. So that in every process, the State is obliged to guarantee the rights of the people as vaccine consumers, both paid and free. Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) requires the 'core obligations' of the States parties to comply with them independently

of their available resources linked to the right to health, including the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. The state needs to assure that all the medical services are provided to the residents.

Moreover, health is currently a wider concept than just curative or rehabilitative services, and preventive public health measures and services covering the social determinants of health play a big role for being and staying healthy. [15] This knowledge creates strong doubts about Rawls arguments regarding health. The attempts to enlarge Rawls theory to cover health as a subject of principles of justice emerge on these grounds [16]. *Salus populi suprema lex esto* is the one of the most popular adages that is usually used which means welfare of the people is the supreme law. The government in order to implement this norm, need to enact legislation, regulate, and adjudicate [17] the public health policy, not limited to Vaccination. In the midst of a health emergency, the State has full control to regulate all forms of health-related policies.

The procurement of vaccines that has just taken place in the last few months has raised various new legal issues in the health sector, starting from their procurement, distribution to the impact of AEFI which the author is currently reviewing in this research. Although in the longer-term supply is not expected to be an issue given the number of vaccines in development, at present, stocks of COVID-19 vaccinations are limited and are not available for private sale. Each State has its own priority list for rolling out the vaccine. Even though, there have been some reports that said some types of vaccines could be available for private purchase in India. While general security. This would make due diligence in vaccine sourcing even more important. [18]

In this study, the author recommends the state to apply the principle of strict liability in ensuring access to justice for the community, especially vaccine consumers. Strict liability can be interpreted as a criminal responsibility by not requiring that the perpetrator is guilty of one or more of the *actus reus*. Strict liability is a liability without fault, not based on the quality of the error, but the focus point is on the occurrence of a violation. In our recommendation, the application of strict liability, we also not only recommend the right to balanced compensation, but also the right to transparency and state responsibility to recognize the impact of vaccines on consumers. The lawsuits do not adhere to a standard in terms of claims, either by requesting reparation for moral damages, sometimes material damages, in other cases both, and in still others, aesthetic damage. Given that this data will also be a national report and evaluation material in an effort to improve the National Vaccination system in the future. Although it cannot be denied that the condition of the national political economy in which Indonesia currently has very large access to vaccine distribution, and this has become special advantages not only for the country but also the people, but we also need to see that currently the data shows that there are still

many people. For those who worry and do not believe in the COVID-19 vaccination program, even the existence of COVID-19 itself is still ignored.

This can be seen from the results of a survey by the Indonesian Political Indicator Survey Institute which showed that from 1,200 respondents in the period 1 to 3 February 2021, as many as 54.9% of respondents were willing to be vaccinated, while a total of 41% of residents were not or less willing. Based on this figure, the recommendations for implementing strict liability are expected to increase public confidence in the vaccination program being implemented by the Government. Not to mention the cases of vaccine counterfeiting that have increased people's concern about vaccines. In addition, by implementing the Strict Liability system in order to provide the highest protection for Vaccine consumers, this means that the state has actively participated in efforts to guarantee the highest protection for its citizens as stipulated in the Constitution and various ratifications of International Conventions.

3.2.3 Implementation of strict liability on Vaccine Consumer Protection

Vaccination complaint settlement scheme through AEFI Indonesian National Commission should not deny state responsibility to victims through the courts. Since the government shows us none of the number of complaints to the National Commission until May 2020, it proves that the victims died due to AEFI. [19] According to the authors' analysis, this data cannot be used as a tool to prove to the public about safety of the vaccine. First, because it potentially could hinder and close the possibility and intention of consumers to reporting their cases and looking for another dispute resolution alternative, such as bringing those cases to the court. Second, relying on this argument on the existing laws and regulations, the state is responsible to guarantee the highest protection for the community in the health sector, either for vaccine users. This publication has become a proof of the lack of state commitment to consumer protection.

This argument actually also departs from the consumer protection legal issues recorded in the Academic Manuscript compiled by the Consumer Protection Agency. The current health legal system in Indonesia is also unable to guarantee full protection for victims. The health responsibility system is supposed to be able to be compared at least with environmental law enforcement (where the victim has inline ability to prove) should be resolved through the strict liability principle.

Table 1 Development of Indonesia Consumer Protection Law

ELEMENT	Responsibilities of Business Actors before Indonesian Consumer Protection Law	Responsibilities of Business Actors from 2000 till now	Responsibilities of Business Actors in the Future
Article and Regulation	Article 1365 of the Civil Code	Article 19 Paragraphs 1,2, 5 and Article 28 of Law of the Republic of Indonesia Number 8 of 1999 on Consumer Protection	Needs comprehensive amendments to Law of the Republic of Indonesia Number 8 of 1999 on Consumer Protection
Main Principle	Liability based on fault	The principle of presumption to always be responsible or can be referred to as the Principle of Semi Strict Liability	Needs justification on Principles of Strict Liability
The burden of proof	The burden of proof lies with the consumer as the Plaintiff.	The burden of proof lies with the Business Actor as a defendant. The business actor as the defendant is always responsible until the business actor can prove otherwise.	What is proven is not an element of fault. Business actors do not prove the element of fault, but whether or not there is a causality between the disadvantage and the product.

From this table we can identify the development of legal consumer protection in Indonesia. In the early wave, Indonesia still adopted the Civil Code article which lies the burden of proof to the consumer. Then this perspective was transformed along with the development of business concepts and actors which were mostly considered to be able to increase profits as much as

possible. Starting from this awareness, then Indonesia created the Indonesian Consumer Law in 1999. This regulation at the same time mandated the establishment of the consumer protection agency and strengthened the consumer position.

But reflecting on the development of science and the political and economic conditions, Indonesia actually is able to level up the guarantee of consumer protection. Consumer protection regulation nowadays is good enough but somehow has weaknesses, especially for health sector consumers. All pharmaceutical products contain an element of flaw and pose a risk of loss to consumers. Also, there is no guarantee that a product is 100% safe. This is why the implementation of the strict liability principle is really needed and urgent. Business actors should be obliged to provide compensation for products that cause harm to consumers whether or not there is an element of error.

The American Court also followed the Restatement theory of strict product liability. [20] Under this theory, an "unavoidably unsafe product" such as the Sabin vaccine-that is, a product that cannot be made safe no matter how carefully it is manufactured-is defective if it is *unreasonably* dangerous. A two-step analysis is required to determine whether the product was "unreasonably dangerous. Departing from this case study is also quite interesting. Where a child who gets the Polio Vaccine, a week after the vaccination the child actually experiences polio (paralysis). Her parents later sued, on the cases Reyes v. Wyeth Laboratories. This case is widely cited in consumer protection analysis. Where the jury ruled that the vaccine producer was held liable for injuries suffered by a polio victim whose illness was allegedly caused by the vaccine itself. Public health officials and producers are responsible for providing requirements that warnings on unavoidably unsafe products, such as vaccines, must include a description of alternatives to the product and of the risks and benefits of the alternatives. Since safety is only one of the many factors to be considered in mass immunization programs.

It becomes more interesting that after this decision, the Texas Department of Health and governmental response to this reluctance, the Article concludes that the public interest in encouraging citizens to participate in mass immunization programs justifies a non-tort compensation system for those injured by the vaccine or its administration.

In addition, this recommendation also departs from the identification of Authors in the application and implementation of product liability that has been implemented in Indonesia. Product liability is the basis for demands for compensation from consumers against business actors. There are three basic claims due to negligence, breach of warranty, and claims based on strict product liability theory. Along with the times, consumer protection law has developed and changed

from a law that is repressive in the form of a fault-based liability principle to a principle that is responsive or in favor of the interests of consumers in the form of absolute responsibility (strict liability).

4. CONCLUSION

Until now (2021), Indonesia has not adopted the concept of strict liability in the consumer protection sector because it still requires an element of error in terms of responsibility based on Article 19 of the Law of the Republic of Indonesia Number 8 of 1999 on Consumer Protection.

Strict liability can be applied by the Government of Indonesia to Covid-19 vaccine products as the embodiment of the highest standard of health protection by the state to citizens in accordance with article 12 of the International Covenant on Economy, Social and Culture (ICESCR) 1966.

The Covid-19 Vaccine can be made with or without any element of error (because it has been made very well according to standard standards) while the Indonesia currently still requires errors with the burden of proof on businesses / defendants as the basis of accountability and compensation. The provision is certainly unfair to consumers because the Covid-19 vaccine can be made without any element of error. By applying the Principle of Strict Liability in the *Law of the Republic of Indonesia Number 8 of 1999 on Consumer Protection*, consumers can claim liability and compensation to businesses without having to require an element of error. So, with the application of the strict liability principle, it is not necessary to prove the element of error in business when there are side effects of vaccines or AEFI. When consumers experience losses in the form of severe side effects due to the Covid-19 vaccine such as disease, limb defects and even death, then businesses / manufacturers / governments can be held accountable and compensated without having to prove the element of error. The use of the strict liability principle in anticipating a dispute over the side effects of the Covid-19 vaccine could pave the way for the inclusion of strict liability principles in consumer protection laws.”

Based on this study, it is clear that relying on the analysis of implementation of strict liability principles in some regulation and also sample cases, so consumer protection of the side effects of the Covid-19 vaccine can be the entrance to the application of strict liability in consumer protection laws.

Recommendation:

1. It is important for the government to work together with Legislative revision or amendments to the Indonesian Consumer Protection Act (ICPA) by including the concept of The Principle of Absolute Responsibility or Strict Liability in the Indonesian Consumer Protection Law
2. The government can conduct a review of what types of products can be subject to strict liability principles.

Especially for health sector products such as COVID-19 Vaccine as it is the responsibility of the state to fulfill human rights in the public health sector.

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